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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/834,008	04/12/2001	Shinichi Mochizuki	10939/2022	4949

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EXAMINER	
KAM, CHIH MIN	
ART UNIT	PAPER NUMBER
1653	

DATE MAILED: 08/23/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/834,008	MOCHIZUKI ET AL.	
	Examiner	Art Unit	
	Chih-Min Kam	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 April 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *6,9-11,13,14,17-20,23-25 and 33-55* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *6,9-11,13,14,17-20,23-25,33-44 and 46-55* is/are rejected.

7)☒ Claim(s) *45* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *7/27/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of the Claims

1. Claims 6, 9-11, 13, 14, 17-20, 23-25 and 33-55 are pending.

Applicants' amendment filed April 7, 2004 is acknowledged, and applicants' response has been fully considered. Claims 6, 9, 11, 13, 14, 17, 19, 20 and 23-25 have been amended, claims 7, 8, 12, 15, 16, 21, 22 and 26-32 have been cancelled, and new claims 33-55 have been added. Therefore, claims 6, 9-11, 13, 14, 17-20, 23-25 and 33-55 are examined.

Objection Withdrawn

2. The previous objection of claims 8, 12, 16, 22, 24, 28 and 32, is withdrawn in view of applicants' cancellation of the claim in the amendment filed April 7, 2004.

Rejection Withdrawn

Claim Rejections-Obviousness Type Double Patenting

3. The previous rejection of claims 7, 8, 12, 15, 16, 21, 22 and 26-32 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3, 7-13, 27, 30-33, 37-43, 57-60 and 64-70 of co-pending application 10/183,091 or 10/364,045, is withdrawn in view of applicants' cancellation of the claim in the amendment filed April 7, 2004.

Claim Rejections - 35 USC § 112

4. The previous rejection of claims 6-32, under 35 U.S.C.112, first paragraph, is withdrawn in view of applicants' cancellation of the claim, applicant's amendment to the claim, and applicant's response at pages 10-12 in the amendment filed April 7, 2004.

5. The previous rejection of claims 7-9, 15-17, 20-25 and 27-29, under 35 U.S.C.112, second paragraph, is withdrawn in view of applicants' cancellation of the claim, applicant's

amendment to the claim, and applicants' response at pages 12-13 of the amendment filed April 7, 2004.

Claim Rejections - 35 USC § 102

6. The previous rejection of claims 6-9 and 12 under 35 U.S.C. 102(a) as being anticipated by Goldenberg *et al.* (WO 98/46211, October 22, 1998), is withdrawn in view of applicants' applicant's amendment to the claim, and applicants' response at pages 12-13 of the amendment filed April 7, 2004.

Claim Rejections-Obviousness Type Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

7. Claims 6, 9-11, 13, 14, 17-20, 23-25, 33-35, 38-44, 46-50, 54 and 55 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3, 7-13, 27, 30-33, 37-43, 57-60 and 64-70 of co-pending application 10/183,091. Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 6, 9-11, 13, 14, 17-20, 23-25, 33-35, 38-44, 46-50, 54 and 55 in the instant application disclose a medicinal composition comprising human OCIF protein or a homolog thereof and a polysaccharide; a method of enhancing the activity of human OCIF

protein or a homolog thereof, a method of treating a bone-pathobolism, a method of lowering the serum calcium level in a subject, or a method for prolonging the persistence of human OCIF protein or a homolog thereof, the method comprising administering the OCIF protein or the homolog thereof and a polysaccharide. This is obvious in view of claims 1-3, 7-13, 27, 30-33, 37-43, 57-60 and 64-70 of the co-pending application which disclose a complex comprising at least one substance of OCIF, an analog thereof and a variant thereof, which is bound to at least one substance of a polysaccharide or a polysaccharide derivative; a pharmaceutical composition comprising the complex and a pharmaceutically active carrier; a method of prolonging the time that OCIF is retained in the bloodstream by administering the complex; and a method for the prophylaxis or treatment of bone metabolic diseases by administering the complex. Both sets of claims cite a medicinal composition comprising human OCIF protein or a homolog thereof and a polysaccharide; a method of enhancing the activity of a human OCIF protein or a homolog thereof, or a method for treating a bone metabolic disease by administering the OCIF protein or a homolog thereof and the polysaccharide. Thus, claims 6, 9-11, 13, 14, 17-20, 23-25, 33-35, 38-44, 46-50, 54 and 55 in present application and claims 1-3, 7-13, 27, 30-33, 37-43, 57-60 and 64-70 in the co-pending application are obvious variations of a medicinal composition comprising a human OCIF protein or a homolog thereof and a polysaccharide; a method of enhancing the activity of a human OCIF protein or a homolog thereof, or a method of treating a bone-pathobolism comprising administering the OCIF protein or a homolog thereof and the polysaccharide.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

8. Claims 6, 9-11, 13, 14, 17-20, 23-25, 33-35, 38-44, 46-50, 54 and 55 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3, 7-13, 27, 30-33, 37-43, 57-60 and 64-70 of co-pending application 10/364,045. Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 6, 9-11, 13, 14, 17-20, 23-25, 33-35, 38-44, 46-50, 54 and 55 in the instant application disclose a medicinal composition comprising human OCIF protein or a homolog thereof and a polysaccharide; a method of enhancing the activity of human OCIF protein or a homolog thereof, a method of treating a bone-pathobolism, a method of lowering the serum calcium level in a subject, or a method for prolonging the persistence of human OCIF protein or a homolog thereof, the method comprising administering the OCIF protein or the homolog thereof and a polysaccharide. This is obvious in view of claims 1-3, 7-13, 27, 30-33, 37-43, 57-60 and 64-70 of the co-pending application which disclose a complex comprising at least one substance of OCIF, an analog thereof and a variant thereof, which is bound to at least one substance of a polysaccharide or a polysaccharide derivative; a pharmaceutical composition comprising the complex and a pharmaceutically active carrier; a method of prolonging the time that OCIF is retained in the bloodstream by administering the complex; and a method for the prophylaxis or treatment of bone metabolic diseases by administering the complex. Both sets of claims cite a medicinal composition comprising human OCIF protein or a homolog thereof and a polysaccharide; a method of enhancing the activity of a human OCIF protein or a homolog thereof, or a method for treating a bone metabolic disease by administering the OCIF protein or a homolog thereof and the polysaccharide. Thus, claims 6, 9-11, 13, 14, 17-20, 23-25, 33-35, 38-44, 46-50, 54 and 55 in present application and claims 1-3, 7-13, 27, 30-33, 37-43, 57-60 and 64-

70 in the co-pending application are obvious variations of a medicinal composition comprising a human OCIF protein or a homolog thereof and a polysaccharide; a method of enhancing the activity of a human OCIF protein or a homolog thereof, or a method of treating a bone-pathobolism comprising administering the OCIF protein or a homolog thereof and the polysaccharide.

In response, applicants request that the Examiner holds these rejections in abeyance until allowable subject matter is indicated (page 10 of the response). Applicants' response has been considered, however, the rejection maintains.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 6, 9-11,13, 14, 17-20, 23-25, 33, 34-39, 46-53 and 55 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the applicant regards as his invention.

10. Claims 6, 9-11, 20, 23-25, 33, 35-37, 39, 52 and 53 are indefinite because of the use of the term "bone-pathobolism". The term cited renders the claim indefinite, it is not clear what the term means, although the specification cites examples of bone-pathobolism such as osteoporosis, hyperclacemia or chronic articular rheumatism (page 1, first paragraph), it does not define the term. Claims 9-11, 23-25 and 39 are included in the rejection because they are dependent on a rejected claim and do not correct the deficiency of the claim from which they depend.

11. Claims 13, 14, 17-19, 34, 38, 46-51 and 55 are indefinite because the claim lack an essential step as claimed in the process of enhancing the activity of OCIF protein or a homolog

thereof, or of prolonging the persistence of human OCIF protein or a homolog thereof in a subject, the method comprising administering to a subject the OCIF protein or the homolog thereof and an effective amount of polysaccharide. The omitted step is the effective amount of human OCIF protein or a homolog thereof administered. Claims 14, 17-19, 38 and 47-51 are included in the rejection because they are dependent on a rejected claim and do not correct the deficiency of the claim from which they depend.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

10. Claims 6, 9-10, 36 and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over by Goldenberg *et al.* (WO 98/46211, October 22, 1998).

Goldenberg *et al.* teach a preparation of a sustained-released composition containing a biologically active agent, a hydrophilic polymer and at least one precipitating agent (page 5, line

23-page 6, line 1), where the preparation contains the steps of dissolving a biological active agent and a hydrophilic polymer with a solvent to form a first mixture (a liquid form), dissolving at least one precipitating agent in a solvent to form a second mixture, and adding the first mixture to the second mixture to precipitate the biologically active agent within the hydrophilic polymer (page 6, lines 15-29). Since the reference teaches the preparation of a liquid mixture of a biological active agent and a hydrophilic polymer (page 6, lines 15-20), and it also indicates a group of biologically active agents including osteoprotegerin (page 10, line 22-page 11, line 27; known as osteoclastogenesis inhibitory factor) and a group of hydrophilic polymers including dextran sulfate, heparin or carrageenan can be used for the preparation of sustained-released composition (page 7, lines 24-page 8, line 17; claims 6, 9 and 10), which can be in a lyophilized form (page 12, lines 28-33; claims 36 and 37), thus at the time of invention was made, it would have been obvious that one of ordinary skill in the art is motivated to dissolve osteoprotegerin and a hydrophilic polymer of dextran sulfate or heparin in a solvent as a first liquid mixture for preparing a sustained-release pharmaceutical composition, which results in the claimed invention and was, as a whole, prima facie obvious at the time the claimed invention was made. The term "for treating a bone-pathobolism" is an intended use, which does not play weight in the claimed composition; and heparin such as a low molecular weight heparin (3000, 4000 or 6000) is commonly used.

12. Claim 45 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

Conclusion

13. Claims 6, 9-11, 13, 14, 17-20, 23-25, 33-44 and 46-55 are rejected, and claim 45 is objected to.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (571) 272-0948. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached at 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Chih-Min Kam, Ph. D.
Patent Examiner

CMK
August 13, 2004